

REMARKS

Claims 1-18 are pending and stand rejected. No amendments have been made.

Claims Objections

Claims 1-3, 14, and 18 are objected to as containing informalities. The Examiner suggests removing the word “the” prior to the phrase “at least one opening” in claims 1-3, 14, and 18.

Applicant respectfully disagrees. The phrase “at least one opening” is a claim element, which is first recited in claim 1. In order to provide proper antecedent basis when referring to this element, the definite article “the” is used prior to later recitations of “at least one opening.” As such, Applicant believes that claims 1-3, 14, and 18 are clearly stated.

Claims Rejections - §102(b)

Claims 1, 5-6, 11-14, and 17 are rejected under 35 U.S.C. § 102(b)¹ as anticipated by U.S. Patent No. 6,488,636 to Bryan et al. (“Bryan”).

The Examiner argues that Bryan teaches “a sampling device with an inner cannula 16 and outer cannula 12 that are selectively moveable, an outer cannula 12 with a closed distal end and penetrating tip 13 and a plurality of openings 114 in the sidewall, an inner cannula 16 is aligned with openings 112 in the sidewall.”

Applicant respectfully disagrees.

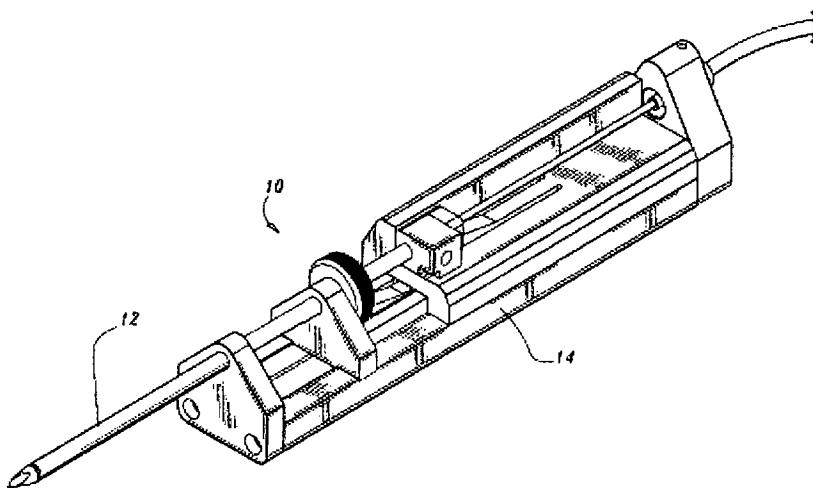
Claim 1 is directed to a bone marrow sampling device that includes an outer and an inner cannula. The outer cannula has a sidewall defining an inner lumen and a closed distal end with a tissue penetrating tip, the sidewall having a plurality of openings formed therein and spaced apart at different radial and longitudinal positions on the sidewall, wherein each opening is in fluid communication with the inner lumen of the outer cannula.

¹ Since the Bryan reference issued/published less than one year prior to the filing date of the instant application, a rejection under §102(b) is improper. It appears that the Examiner may have intended to refer to §102(e).

The inner cannula has a sidewall defining an inner lumen, the inner cannula being adapted to be disposed within and mated to the outer cannula such that the outer cannula and the inner cannula are selectively movable with respect to each other. At least one opening is formed in the side wall of the inner cannula.

The device allows a user to draw bone marrow from different radial and longitudinal positions external to the sidewall of the outer cannula without the need to reposition the outer cannula. In particular, selective relative movement of the inner cannula and the outer cannula enables the device to be configured in multiple bone marrow sampling modes in which the at least one opening in the sidewall of the inner cannula is aligned with different openings in the sidewall of the outer cannula.

Conversely, the Bryan reference is directed to a soft tissue biopsy apparatus and lacks several of the elements recited in claim 1. For example, the Bryan reference lacks an outer cannula with a closed distal end having a tissue penetrating tip. In an attempt to meet this limitation the Examiner points to reference number 12, Bryan's "insertion portion." (Figure 1, showing insertion portion 12 is reproduced below.)



However, as shown in Figures 2 through 4, the insertion portion is assembled from several concentric tubes including an outer cutting tube 24, an inner thrust tube 16, and a basket tube 18 positioned therebetween. The outermost tubes, cutting tube 24 and basket tube 18, have *open distal ends* and do not have a *cutting tip*. Rather, it is Bryan's innermost tube, thrust tube 16, which includes penetrating tip 13. Thus, Bryan discloses no outer cannula meeting the limitations of claim 1. As such, Bryan's disclosure fails to anticipate claim 1.

Moreover, since the device disclosed in the Bryan reference is specifically configured such that the inner thrusting tube has a tissue penetrating tube, one skilled in the art would have no motivation to place a tissue penetrating tip on the outer cutting tube. In order for Bryan's device to sample tissue, the outer cutting tube (24) has to have the ability to slide over the inner tubes (16, 18) in a proximal-to-distal direction. If the outer cutting tube had a closed distal end with a tissue penetrating tip, the outer tube would not have the ability to slide over the inner tubes and cut away a tissue sample. As such, any attempt to reconfigure Bryan's device to meet the claimed outer cannula with closed distal end having a tissue penetrating tip would be at odds with the disclosure of Bryan.

The Bryan reference also fails to disclose a device where selective relative movement of an inner cannula and an outer cannula enables the device to be configured in multiple bone marrow sampling modes, such that bone marrow can be drawn into an inner lumen of the inner cannula from different radial and longitudinal positions. While Bryan discloses holes 114 in basket tube 18 and holes 112 in thrust tube 16, the basket tube and the trust tube do not rotate relative to one another. Instead, Bryan's device is configured so that a razor blade 106 "prevents relative rotation between thrust tube 16 and basket tube 18." Col. 7, lines 51-52. Thus, Bryan

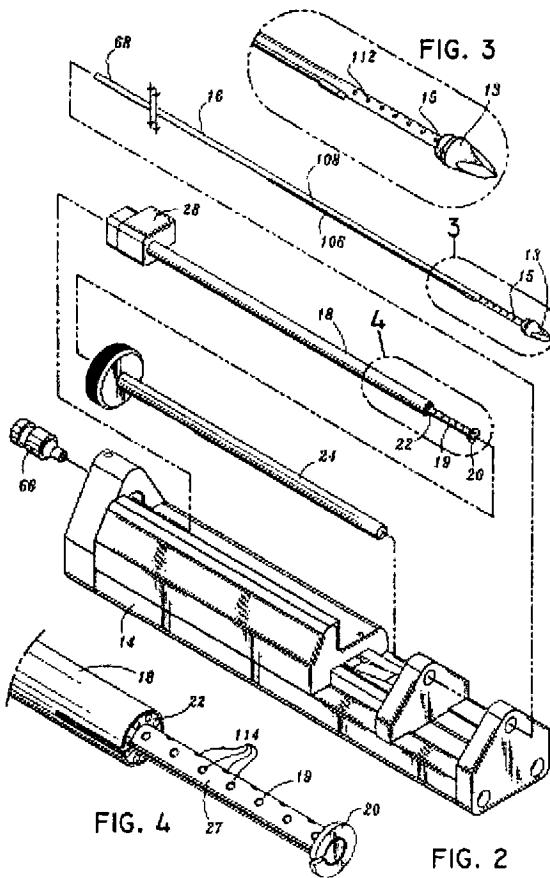


FIG. 2

also fails to disclose the selective relative movement of the inner and outer cannulas required by claim 1. In fact, Bryan's device is configured to prevent such movement.

Accordingly, Bryan's device does not suggest or disclose the limitations of claim 1 and Applicant respectfully requests withdrawal the rejection of independent claim 1 in view of Bryan. In addition, Applicant believes claims 2 through 18, are allowable at least because they depend from an allowable base claim.

Claims Rejections - §103(a)

Dependent claims 2-4, 7-10, 15-16, and 18 are rejected under 35 U.S.C. § 103(a) as obvious over Bryan in combination with a secondary reference or references.

In particular, the Examiner cites U.S. Patent Application Publication No. 2003/0050574 to Krueger ("Krueger") to teach the size and configuration of the withdrawal apertures set forth in claim 2-3, 7 and 18. Krueger is generally directed to a biopsy instrument having an inner sampling cannula with open trough-like portion and an outer cannula with *an open distal end*. Accordingly, Krueger fails to remedy the deficiencies of Bryan set forth above. In particular, Kreuger does not suggest an outer cannula with a closed distal end having a tissue penetrating tip. In addition, only Krueger's inner cannula has openings. As such, Krueger does not suggest or disclose selective relative movement between an inner and outer cannula that allows for multiple bone marrow sampling modes. Accordingly, even if combined, the combination of Krueger and Bryan would not anticipate claim 1.

U.S. Patent Application Publication No. 2003/0093008 to Van Bladel et al. ("Van Bladel") is cited to teach the dimensions of the outer cannula as set forth in claim 4. However, Van Bladel fails to suggest or disclose an outer cannula with a closed distal end having a tissue penetrating tip. Instead, Van Bladel is generally directed to a tissue biopsy tool with an outer cannula having an *open distal end* and an inner biopsy needle with a tissue penetrating distal tip. As such, Van Bladel's does not suggest the user of an outer cannula with a closed distal end having a tissue penetrating tip. In addition, Van Bladel lacks any reference to selective movement between an inner and outer cannula which allows a user to draw sample from different radial and longitudinal positions external to the outer cannula. Accordingly, even if

Van Bladel could be combined with Bryan, the combination would fail to disclose the limitations of claim 1.

U.S. Patent No. 5,810,826 to Akerfeldt et al. (“Akerfeldt”) is cited to teach an inner and outer cannula with translational and rotational movement. Akerfeldt is generally directed to a device for puncturing cortical bone and includes an outer cannula having *an open distal end* and an inner needle. The needle can include an eccentrically shaped tip. However, nowhere does Akerfeldt teach or disclose the limitation of claim 1 lacking in Bryan. Accordingly, Akerfeldt also fails to remedy the deficiencies of Columbus.

U.S. Patent Application No. 2002/0016555 to Ritchart et al. (“Richart”) is cited to teach a channel in a sidewall for delivery of treatment material and automated movement of an inner and outer cannula. Ritchart is directed to a soft tissue biopsy device having a hollow outer piercing needle (20) and an inner cutter (22) having a lumen. The outer piercing needle includes a single tissue receiving port, while the inner cutter does not have any apertures in its sidewall. While Richart’s outer needle has a closed distal end, one of ordinary skill in the art would have no motivation to substitute Richart’s closed ended needle for Bryan’s open ended outer cannula. As discussed above, Bryan’s device requires an open ended outer cannula because a closed ended outer cannula would result in a non-functioning device. Thus, any such substitution would be improper.

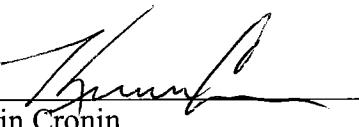
In addition, Richart does not disclose selective relative movement between an inner and outer cannula which enables a device to be configured in multiple bone marrow sampling modes such that openings in the sidewall of the inner cannula can be aligned with different openings in the sidewall of the outer cannula. Instead, Richart discloses an inner cutting cannula without any openings in its sidewall. As such, even if Bryan and Richart could be combined, the combination would fail to anticipate claim 1.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections of the claims and to pass this application to issue. However, should any outstanding issues remain, Applicant asks that the Examiner please contact the undersigned Attorney for Applicant.

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Respectfully submitted,

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